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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/594,361

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Jon Erik Braenden

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EXAMINER

VALENROD, YEVGENY

ART UNIT

PAPER NUMBER

1621

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/594,361	<b>Applicant(s)</b> BRAENDEN ET AL.	
	<b>Examiner</b> YEVEGENY VALENROD	<b>Art Unit</b> 1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 03 August 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1,3-15,17,19-27,29-33,35-37,39-48 and 50-58 is/are pending in the application.
- 4a) Of the above claim(s) 20-23,29,32,33,41-48 and 50 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-7,9-11,17,19,24-27,35 and 36 is/are rejected.
- 7) ☒ Claim(s) 8,12-15,30,31,37,39,40 and 51-58 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 September 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

The following is a final office action in application # 10/594,361.

Rejection of claim 15 under 35 USC 112 2<sup>nd</sup> paragraph is withdrawn upon further consideration and in view of applicants' remarks.

The double patenting rejection is withdrawn in par. Only claims 24 and 25 are subject to the double patenting rejection over us patents 7,287,646 and 7,217,736

Rejection of claims 1-19, 24-27, 30, 31, 34-40 and 49 under 35 USC 103(a) over Gierscky et al in view of Berge et al. is withdrawn in view of applicants' amendments and remarks. Examiner finds that the instantly claimed acid addition salts of 5-ALA exhibit unexpected properties when compared to the salts found in the art.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 4-6 depend of canceled claim

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2, the limitations of those claims are therefore unclear. For the purpose of advancing prosecution examiner will interpret claim 4-6 as depending on claim 1. Appropriate correction is required.

Claims 9-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claims 9-11 the substituent R<sup>1</sup> has not been defined. The scope of the claim is therefore unclear. For the purpose of advancing prosecution Examiner will interpret the definition of R<sup>1</sup> to be the same as presented in claim 1.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 5-7, 17, 19, 24- 27, 35 and 36 rejected under 35 U.S.C. 102(b) as being anticipated by Takeya (Unexamined Japanese patent application H4-9360, disclosure date 1/14/1992; already of record).

Takeya discloses a small genus of compounds from which one skilled in the art would readily envision the compounds and compositions of the instant

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claims. A compound of formula (I) and its salt is presented in the first claim (page 2, claim 1). Definitions for the substituents are:

R1 = alkyl group of 2 or more carbons

R2 = H

The acid for forming a salt is selected from HCl, sulfuric acid, nitric acid and a few carboxylic acids (page 4, second paragraph from the bottom).

Takeya also describe preparing solutions of the 5-ALA salts. Solvents for the solutions are listed in paragraph 3 on page 9 and include pharmaceutically acceptable solvents such as water and lower alcohols.

Although Takeya fails to present as part of the examples a single specie that anticipates the instant claims, the disclosure of a very limited number of possibilities is considered anticipatory

“When the compound is not specifically named, but instead it is necessary to select portions of the teachings within a reference and combine them, e.g., select various substituents from a list of alternatives given for placement at specific sites on a generic chemical formula to arrive at a specific composition, anticipation can only be found if the classes of substituents are sufficiently limited or well defined” *Ex parte A*, 17 USPQ2d 1716 (Bd. Pat. App. & Inter. 1990)

“If one of ordinary skill in the art is able to “at once envisage” the specific compound within the generic chemical formula, the compound is anticipated.” *In re Petering*, 301 F.2d 676, 133 USPQ 275 (CCPA 1962)

In the instant case one can “at once envision” the claimed compound and/or composition and the claims are properly rejected under 35 USC 102(b).

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 24 and 25 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 10 and 19 of U.S.

Patent No. 7,287,646. Although the conflicting claims are not identical, they are not patentably distinct from each other.

Instant claims differ from claims of '646 in that the instant claims are directed to salts of 5-ALA, while claims of '646 are directed to free bases.

### **Obviousness**

Its obvious to prepare an acid salt of a free base where the free base is a known pharmaceutically active agent. Preparing a salt is known to alter properties such as solubility and stability of a pharmaceutically active agent.

Claims 24-25 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 7 of U.S. Patent No. 7,217,736. Although the conflicting claims are not identical, they are not patentably distinct from each other.

Instant claims differ from claims 1 and 7 of '736 in that the instant claims are directed to a salt of 5-ALA while the claims of '736 are directed to free bases.

Obviousness

Its obvious to prepare an acid salt of a free base where the free base is a known pharmaceutically active agent. Preparing a salt is known to alter properties such as solubility and stability of a pharmaceutically active agent.

***Reply to applicants' remarks regarding the double patenting rejections:***

Applicants have argued that the claims have been amended to overcome the double patenting rejections. While the amendment to claim one has limited the scope of 5-ALA esters to those outside of the scope of '736 and '646 patents, the ALA derivatives of claim 24 and 25 are not subject to the same amendment as claim 1 and the double patenting rejection is therefore maintained.

### ***Claim Objections***

Claims 8, 12-15, 30, 31, 37, 39, 40 and 51-58 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

### ***Conclusion***

Claims 1, 3-15, 17, 19-27, 29-33, 35-37, 39-48 and 50-58 are pending.

Claims 1, 3-7, 9-11, 17, 19, 24-27, 35 and 36 are rejected.

Claims 8, 12-15, 30, 31, 37, 39, 40 and 51-58 are objected to.

Claims 20-23, 29, 32, 33, 41-48 and 50 are withdrawn.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will



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the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yevgeny Valenrod whose telephone number is 571-272-9049. The examiner can normally be reached on 8:30am-5:00pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Daniel Sullivan can be reached on 571-272-0779. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Yevgeny Valenrod/

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